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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/644,456	08/24/00	HORNIK V	2254-031

020582
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HM12/1102

EXAMINER	
BORIN, M	
ART UNIT	**PAPER NUMBER**
1631	4

DATE MAILED: 11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/644,456	Applicant(s) Hornik et al.
	Examiner Michael Borin	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: Sequence Listing Letter

Part III DETAILED ACTION

Claims 1-28 are currently pending.

It is noted that claims 21,28, which are seemingly intended to be drawn to methods of use of products of claim 1, are not limited to use of a product of the same scope as the product of claim 1. For purposes of restriction requirement, the method claims are considered here as drawn to method of use of products of claim 1. Applicant is requested to bring method claims in accordance with the product claims; otherwise, a further restriction requirement will be issued.

Please see the attached NOTICE TO COMPLY WITH SEQUENCE RULES which sets its own period for response.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-6 will be examined together with one of the following product groups I-III:

I. Claims 7-11,15-18, drawn to peptides of formula 1 having a cyclized moiety and their compositions, classified in class 530, subclass 317.

II. Claims 12,19, drawn to peptides of formula ~~2~~ 3 having a cyclized moiety and their compositions, classified in class 530, subclass 317.

III. Claims 13,20 drawn to peptides of formula ~~3~~ 4 having a cyclized moiety and their compositions, classified in class 530, subclass 317.

Claims 21,28 will be examined with one of the following method groups IV.1-VI.6.

IV. Claims 22-25 drawn to method of treatment using peptides of formula 1 having a cyclized moiety, classified in class 530, subclass 317. Group IV is further restricted into following groups according to the respective disorders:

IV.1 Method of treatment of neoplasms.

IV.2 Method of treatment of bacterial infections.

IV.3 Method of treatment of parasite infections.

IV.4 Method of treatment of viral infections.

IV.5 Method of treatment of chronic autoimmune disorders.

IV.6 Method of treatment of osteoporosis.

V. Claims 12,19, drawn to method of treatment using peptides of formula 2 having a cyclized moiety, classified in class 514, subclass 09. Group V is further restricted into following groups according to the respective disorders:

V.1 Method of treatment of neoplasms.

V.2 Method of treatment of bacterial infections.

V.3 Method of treatment of parasite infections.

V.4 Method of treatment of viral infections.

V.5 Method of treatment of chronic autoimmune disorders.

V.6 Method of treatment of osteoporosis.

VI. Claims 13,20 drawn to method of treatment using peptides of formula 3 having a cyclized moiety, classified in class 514, subclass 09. Group VI is further restricted into following groups according to the respective disorders:

VI.1 Method of treatment of neoplasms.

VI.2 Method of treatment of bacterial infections.

VI.3 Method of treatment of parasite infections.

VI.4 Method of treatment of viral infections.

VI.5 Method of treatment of chronic autoimmune disorders.

VI.6 Method of treatment of osteoporosis.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are patentably distinct from each other because of the materially different structures of the compounds they are claiming. The products of Groups II and III do not require presence of Tyr, as residue equivalent to R^{257} in formula 1. Products of Group II and III require different number of backbone residues (4 and 5, respectively) in the cyclized moiety. These compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture. A reference teaching products of one group will not teach or suggest a product of another group.

Methods of use IV.1-IV.6 or V.1-V.6 or VI.1-VI.6 are drawn to methods of treatment of at least 6 patentably distinct disorder conditions and are patentably distinct because the disorder conditions are not related to each other, have different mechanisms of development and etiology, and the methods of treatment have

different enablement requirements. The groups require different literature search and a reference teaching treatment of one disorder (e.g., osteoporosis) will not teach treatment of any other disorder (e.g., parasite infection or autoimmune disease).

Inventions I and IV.1-IV.6, or II and V.1-V.6, or III and VI.1-VI.6 are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of use can be practiced with a broad variety of drugs beyond claimed peptides; methods IV.1-IV.6 or V.1-V.6 or VI.1-VI.6 are alternate methods of using the compound of Groups I, II and III, respectively; the products as claimed can be used in a materially different processes such as peptide synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Species Requirement

Election of species should be required prior to a search on the merits in all applications containing both species claims and generic or Markush claims.(MPEP 808.01(a))

Upon election of any single one of the Groups from above the following election of species is hereby required for the initial search for examination on merits:

The claims of Groups are generic to a plurality of disclosed patentably distinct species of peptides, such as those in claims 7-10, that require a burdensome

classification, and/or bibliographic, manual and computer search. Accordingly, regardless of which group is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., a single compound), even though the requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

October 31, 2001

mlb